# DEPARTMENT OF HEALTH AND HUMAN SERVICES DEPARTMENTAL APPEALS BOARD

# DECISION OF MEDICARE APPEALS COUNCIL Docket Number: M-17-8596

In the case of	Claim for
N.S. (Appellant)	Supplementary Medical Insurance Benefits (Part B)
Nancy Smith	XXX-XX-2399A
(Beneficiary)	(HIC Number)
CGS	1-6376101653
(Contractor)	(ALJ Appeal Number)

The Administrative Law Judge (ALJ) issued a decision dated August 16, 2017, concluding that Medicare Part B did not cover sensors and a transmitter that the appellant-beneficiary received on July 11, 2016, and November 10, 2016, for a Dexcom G4 continuous glucose monitoring (CGM) system.

The appellant has asked the Medicare Appeals Council (Council) to review the ALJ's decision. The appellant's request for review is admitted into the administrative record as Exhibit (Exh.) MAC-1.

The Council reviews the ALJ's decision de novo. 42 C.F.R. § 405.1108(a). As set forth below, the Council agrees with the ALJ's conclusion that the items at issue are not covered by Medicare. However, we modify the ALJ's decision to clarify the basis for this conclusion.

# LEGAL BACKGROUND

Medicare is a defined benefits program. Section 1832(a)(1) of the Social Security Act (Act) provides that benefits under Medicare Part B include "medical and other health services." Section 1861(s)(6) of the Act defines "medical and other health

services" as including durable medical equipment (DME). Section 1861(n) of the Act lists certain items that are classified as DME. However, by its own terms, section 1861(n) is not an exhaustive list of those items that qualify as DME. Thus, the fact that an item is not listed in section 1861(n) does not necessarily mean that it is not DME.

The regulations define DME as equipment that:

- can withstand repeated use;
- has an expected life of at least three years;
- is primarily and customarily used to serve a medical purpose;
- generally is not useful to an individual in the absence of an illness or injury; and
- is appropriate for use in the home.

42 C.F.R. § 414.202 (emphasis added). A device or system which does not comply with all the terms of this definition does not fall within the statutory DME benefit of the Medicare program.

To receive Medicare coverage, a device must first meet the definition of DME, and must also be medically "reasonable and necessary" for the particular beneficiary and in fact be used in the beneficiary's home. Medicare Benefit Policy Manual (MBPM), CMS Pub. 100-02, Ch. 15, § 110. A claim for a device or system which meets the definition of DME would thus only be covered by Medicare when used by a beneficiary for medical purposes.

The CMS Administrator from time to time issues Rulings that serve as precedent final opinions and official statements of agency policy and interpretation. On January 12, 2017, after the dates of service at issue here, the CMS Administrator issued a Ruling addressing whether any CGM systems constituted DME. The Ruling¹ states:

The FDA recently approved expanding the indications of one CGM product to include replacement of blood glucose monitors for diabetes treatment decisions. This Ruling addresses whether 'therapeutic' CGMs, which provide information that can be used to make diabetes treatment decisions meet the definition of

https://www.cms.gov/Regulations-and-Guidance/Guidance/Rulings/Downloads/CMS1682R.pdf (last visited May 7, 2018).

DME. For the purpose of this Ruling, all CGMs that are approved by the FDA for use as adjunctive devices to complement, not replace, information obtained from blood glucose monitors in making diabetes treatment decisions are referred to as 'non-therapeutic' CGMs.

CMS Ruling 1682-R at 7. The 2017 Ruling further states that such "therapeutic" CGM systems will be considered DME if the CGM system is "approved by the FDA for use in place of a blood monitor for making diabetes treatment decisions[;]" generally is not useful to the individual in the absence of an illness or injury; is appropriate for use in the home; and includes a durable component. CMS Ruling 1682-R at 13-14 (emphasis added). In all other cases in which a CGM does not replace a blood glucose monitor for making diabetes treatment decisions, a CGM is not considered DME.

CMS issues national coverage determinations (NCDs) to specifically address certain items and services. "An NCD is a determination by the Secretary of whether a particular item or service is covered nationally under Medicare." 42 C.F.R. § 405.1060(a). "NCDs generally outline the conditions for which an item or service is considered to be covered (or not covered) under § 1862(a)(1) of the Act or other applicable provisions of the Act." Medicare Program Integrity Manual (MPIM), CMS Pub. 100-08, Ch. 13, § 13.1.1. NCDs are binding on all contractors, ALJs, and the Council. 42 C.F.R. § 405.1060(a)(4).

No NCD addresses whether CGM devices or systems qualify as DME or are covered under Medicare. By contrast, the Act has explicitly included home blood glucose monitors as DME and a current NCD spells out the conditions and limitations under which such monitors and associated supplies may be covered. Act § 1861(n); Medicare NCD Manual, CMS Pub. 100-03, § 40.2 (NCD 40.2). CGM devices do not test or monitor blood glucose, but rather monitor interstitial fluid for glucose values, a critical distinction we discuss in more detail later. See generally CMS Ruling 1682-R at 6.

A Medicare administrative contractor may issue a local coverage determination (LCD) that "is a decision . . . whether to cover a particular item or service on a [contractor]-wide, intermediary wide or carrier-wide basis in accordance with Section 1862(a)(1)(A) of the [Act] (i.e., a determination as to whether the item or service is reasonable and necessary.)" MPIM, Ch.

13, § 13.1.3. LCDs speak only to whether and in which circumstances an item or service meets the coverage requirement of being medically reasonable and necessary for beneficiaries' conditions. Information that is not related to reasonableness and necessity criteria, including whether an item falls within a benefit category or is governed by a statutory exclusion, is published through an associated policy article. Id. LCDs thus would not address whether a device or system falls within the Medicare definition of DME at all, as opposed to whether or when an item of DME is covered under Medicare for use by a beneficiary. ALJs and the Council are not bound by, but are required to give "substantial deference" to, applicable LCDs and other CMS program guidance including program memoranda and manual instructions. 42 C.F.R. § 405.1062(a).

The relevant DME contractor published an LCD relating to glucose monitors applicable during the dates of service at issue: L33822 (applicable from Oct. 1, 2015). The LCD provides that home blood glucose monitors will be considered medically reasonable and necessary for a beneficiary only if the beneficiary has diabetes and is trained to use the home monitor. The LCD also specifies that payment for any glucose monitor will be denied as not medically reasonable and necessary if those two "basic coverage criteria" are not present.

The LCD refers to an associated policy article which contains non-medical necessity provisions applicable to glucose monitors. This policy article specifies that CGMs (coded as A9276-A9278) "are considered precautionary and therefore non-covered under the DME benefit." Policy Article A52464.

<sup>&</sup>lt;sup>2</sup> An LCD may list relevant HCPCS codes to identify products, supplies, and services, including items of DME, being addressed. The HCPCS was developed by CMS for processing, screening, identifying, and paying Medicare claims. 42 C.F.R. § 414.40. HCPCS is not a methodology or system for making coverage or payment determinations and the development of codes is independent of the coverage determination process. The mere existence of a code for an item or service does not constitute a determination regarding medical necessity, coverage or payment.

Active LCDs are available at https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx; retired LCDs are available at https://localcoverage.cms.gov/mcd\_archive/ (both last visited May 7, 2018). Associated policy articles can be accessed from the same pages.

## BACKGROUND AND PROCEDURAL HISTORY

## 1. The CGM at issue

In order to manage diabetes, individuals need to test their levels of blood glucose at varying intervals and determine what treatment in terms of diet and/or insulin is appropriate. For those who need to test frequently, home blood glucose monitors may "enable certain patients to better control their blood glucose levels by frequently checking and appropriately contacting their attending physician for advice and treatment." NCD 40.2. These meters use blood drops placed by the patient on specially treated reagent strips to measure color changes and report blood glucose levels. *Id*.

A CGM does not measure blood glucose at all; rather, it estimates, on a continuous basis, the level of glucose in "interstitial" fluid. A CGM has three basic components: a disposable sensor, placed under the skin, that generates an electrical signal in response to the amount of interstitial glucose present and converts that signal into a glucose measurement; a transmitter to which the sensor's information is relayed; and a receiver (or monitor) that is wirelessly connected to the transmitter and receives the interstitial glucose measurement from the transmitter and displays it to the user. If the glucose levels are high or low, depending on the brand/model, a user may be required to confirm those levels with a finger-stick before taking appropriate action.

Individuals who face daily challenges in managing glycemic levels and trying to avoid hypoglycemic and hyperglycemic episodes may benefit from the use of continuous glucose monitoring. Because continuous access to the blood is impractical, CGMs may provide such individuals with notice to test when levels appear problematic, as well as compiling data on glucose levels over time. However, until recently (as explained later in relation to the 2017 Ruling), treatment actions could not be based on CGM readings without direct blood testing.

# 2. The appellant's claim

The record indicates that the appellant is a type 1 diabetic who cannot tell when her blood sugar levels are dropping dangerously low. Exh. MAC-1 at 2-3. To manage her condition the appellant

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uses a CGM system. Id. Specifically, the appellant's physician explained that:

The patient is a highly motivated individual and is working hard to improve her glycemic control. demonstrated over and over again her ability to frequently self-monitor her sugars and follow her physician's recommendations. She has attended comprehensive diabetic education. Despite these measures, her type 1 diabetes remains very difficult to manage which is no fault of her [own]. She innately has wide swings in glucose values from very high to very low. She also has severe nocturnal hypoglycemia, recurrent episodes of severe hypoglycemia and often times is unaware when her sugar is dropping low, placing her at great risk for injury. She also has spikes of sugar in the morning "dawn phenomenon." She has frequent endocrine visits with multiple alternations in her insulin regimen in hope to optimize her care.

Initiation of the DEXCOM sensor has been a huge boon in diabetes care, dramatically lowering the amount of hypoglycemic episodes from 33% to 3-4% just a few months. This has limited her need for hospitalizations, cut out home MEDIC visits (previously quite frequent), has lowered her risk of injury, and has helped her achieve greater glycemic control, lowering her future risk of microvascular complications (retinopathy, neuropathy, end-stage renal disease).

The DEXCOM CGM has been a life saving measure and I strongly believe this is a medical necessity for this patient. It would be disservice to not provide coverage for this device. If the patient is unable to afford the device it would undoubtedly lead to high future medical care costs for this patient, far outweighing the cost of the sensor and supplies.

### *Id*. at 2.

At issue here are sensors (code A0276) and a transmitter (code A9277) that the appellant received on July 11, 2016, and November 10, 2016, for use with a Dexcom G4 CGM receiver. Exh.

1 at 14; Hearing CD. Initially and on redetermination, the contractor denied coverage for these items and determined that the appellant was financially responsible for them. Exh. 1 at 15. In denying coverage the contractor explained that the items did not meet the definition of DME. Id. Upon reconsideration, a Qualified Independent Contractor (QIC) concurred in the contractor's assessments that the items were not covered and that the appellant was financially responsible for the items. Id. at 4. Citing to LCD L11520, the QIC explained that Medicare did not cover the items because CGM systems "are considered precautionary and therefore non-covered under the DME benefit."

Following a hearing, the ALJ ruled that Medicare did not cover the CGM items and that the appellant bore financial responsibility for their costs. Dec. at 8. In support, the ALJ first noted that under policy article A52464 CGM systems "'are considered precautionary and therefore non-covered under the DME benefit.'" Id. at 7. The ALJ then noted that, in order for a CGM system to be covered under the CMS Ruling, "the CGM [system] must be approved by the FDA for use in place of a blood glucose monitor for making diabetes treatment decisions." Id. The ALJ found that the appellant's Dexcom G4 CGM system did not meet this standard because "[a]t this time, the Dexcom G5 system is the only CGM that has FDA approval to be used as a replacement for fingerstick blood glucose testing." Id. at 7-8.

Before the Council, the appellant argues that CGM is medically necessary for her and cost-effective for Medicare. Exh. MAC-1 at 1, 3. In addition, the appellant asserts that she was unaware that Dexcom produced a "better device that Medicare would pay for" and requests an in-person hearing to explain why a CGM system is medically necessary for her. Id. at 3.

### DISCUSSION

As a preliminary matter, we deny the appellant's request for a hearing; the Council does not hold hearings. The Council may hold an oral argument, but only will do so if we decide that the case raises an important question of law, policy, or fact that cannot be readily decided based on written submissions alone. 42 C.F.R. § 405.1124. This case does not present a question of law, policy, or fact that cannot be decided based on the administrative record, as explained in more detail below. We also clarify that the sole issue before us is whether Medicare

covers the sensors and transmitter that the appellant received on July 11, 2016, and November 10, 2016, for use with a Dexcom G4 CGM system. We cannot address coverage for CGM supplies that the appellant received on other dates or looks to purchase in the future or speak generally to whether a different CGM system would be covered by Medicare.

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Turning then to whether Medicare covers the sensors and transmitter that the appellant received on July 11, 2016, and November 10, 2016, we conclude that Medicare does not cover those items. However, we modify the ALJ's decision to clarify the basis for denial, as described below.

## Coverage

1. The determination of whether a device meets the definition of DME depends on the nature and purpose of the device, not the individual beneficiary's usage or clinical condition.

The appellant has emphasized throughout her appeal that, in her particular case, she and her doctors believe that the use of this CGM is reasonable and necessary for her medical condition, specifically as a type 1 diabetic with a history of hypoglycemic unawareness. We recognize the appellant thus feels that her CGM system and associated sensors and transmitter were medically reasonable and necessary for her to manage her blood sugar levels.

The appellant's individual medical condition, however, is not at issue in this case. Before any question can arise of whether an item of DME may be reasonable and necessary for medical treatment under particular conditions, or if whether an individual beneficiary's medical condition has been shown to meet those conditions, a particular device must meet the definition of DME.

The determination of whether an item falls within the definition of a statutory benefit category is fundamental to the nature of Medicare as a defined benefit program and its resolution cannot vary from one beneficiary to another. The benefits available under Medicare are defined on a program-wide basis. By contrast, an item or service that falls within one of the defined benefits may or may not be reasonable and necessary to treat a particular beneficiary's clinical condition, a question often briefly summarized as "medical necessity." LCDs, as

explained earlier, are issued by contractors to help clarify what circumstances and clinical conditions demonstrate medical necessity for a covered benefit. Before a device like a CGM system can be the subject of an LCD at all, however, it must fall in a defined benefit category.

The focus of our analysis, therefore, must be not on how this beneficiary used the device, but on whether the device met all the definitional requirements of DME (the only statutory benefit category under which the appellant sought to claim coverage).

2. CMS has consistently interpreted the definition of DME as excluding CGMs not approved for therapeutic use.

We begin our analysis with the principle underlying CMS's treatment of CGMs, i.e., that, DME must "primarily and customarily used to serve a medical purpose." 42 C.F.R § 410.202. CMS has concluded that some devices that may be useful to patients, and may provide reassurance or guidance or backup in various ways, may nevertheless not constitute DME serving a medical purpose. The MBPM provides some examples of equipment that is "presumptively nonmedical" such as equipment that serves "comfort or convenience functions," "physical fitness equipment (such as an exercycle)," or "precautionarytype equipment (such as preset portable oxygen units)." MBPM, Ch. 15, § 110.1(B)(2).4 Such equipment is not DME even if it may have "some remote medically related use." Id.; see also NCD 280.1, explaining that preset (as opposed to adjustable) oxygen units are not DME because they are "precautionary equipment; essentially not therapeutic in nature."

Where regulatory language is subject to more than one interpretation, the agency invested with expertise in the subject matter is entitled to apply a reasonable reading, so long as it is a permissible construction of the statutory regime. See, e.g., Select Specialty Hosp. of Atlanta v. Thompson, 292 F.Supp.2d 57, 64 (D.D.C. 2003) (citing Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837, 843 (1984)). In Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., the Supreme Court established that, if Congress has not "'directly spoken to the precise"

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 $<sup>^4</sup>$  Other devices are identified in the MBPM as presumptively medical, including respirators, wheelchairs, and hospital beds.  $\mathit{Id}$ . at § 110.1(B)(1). In other cases, information may need to be developed to determine into which category a device falls.  $\mathit{Id}$ . at §110.1.

question at issue," then courts "must defer to a 'permissible' construction of the statute by the agency. Chevron, 467 U.S. 837, 843 (1984).

Such deference is particularly appropriate where the statutory and regulatory scheme most depends on agency expertise. As the District Court in Maryland has explained, "deference to the Secretary's interpretations of Medicare regulations is 'all the more warranted,' because Medicare 'is a complex and highly technical regulatory program, in which the identification and classification of relevant criteria necessarily require significant expertise and entail the exercise of judgment grounded in policy concerns.'" Almy v. Sebelius, 749 F. Supp.2d 315, 324 (D. Md. 2010) (quoting Dist. Mem'l Hosp. of Southwestern N.C. v. Thompson, 364 F.3d 513, 518 (4th Cir.2004); Thomas Jefferson Univ. v. Shalala, 512 U.S. 504, 512 (1994)). "Courts consistently defer to the Secretary in recognition of her broad statutory authority over Medicare coverage matters . . . ." Almy at 324 n.2 (citing Heckler v. Ringer, 466 U.S. 602, 617 (1984)).

We note that at least one court appears to have substituted an interpretation of the phrase "primarily and customarily used to serve a medical purpose" as merely meaning that a device does not have an obvious purpose that is unrelated to health. e.g., Whitcomb v. Hargan, Civ. No. 17-CV-14, slip. op. at 11 (October 26, 2017) (DME definition is "clear on its face" in that a "device's primary and customary purpose must be medical as opposed to non-medical.") We disagree. If this requirement merely meant that DME devices must have health-related uses, there would be no point to the further regulatory requirement that a device "generally is not useful to an individual in the absence of an illness or injury." 42 C.F.R. § 414.202. Regulatory language should be read in a manner that gives meaning and effect to all its terms. We conclude that CMS reasonably and within its authority interpreted the regulatory definition of DME to mean that CGM devices must essentially serve or add to therapeutic measures rather than merely be of some medical or health-related use.

CMS has expressed a consistent interpretation of the definition of DME as limited to those CGM devices which are suitable for direct determination of treatment actions. That interpretation was embodied in the policy article explaining that such CGMs (the kind the appellant used during the dates of service) were

not DME because they were "precautionary." While "precautionary" may be a less than felicitous term in this context, the meaning is not unreasonable. Oxygen units, like glucose monitors, are unlikely to be used in the absence of disease. Preset portable oxygen units may provide additional mobility and convenience which may, in some instances, be very important to a patient, but they do not add any treatment modality or function because they cannot be adjusted to respond to treatment needs. CGM systems like the one the appellant was using may provide information, including alerts, about blood sugar fluctuations, but they similarly do not add any treatment modality or function so long as the patient is required to return to blood glucose measures to make treatment decisions. Where an individual must still use another device to accomplish the medical purpose at issue (i.e., measuring the glucose in the individual's blood), the device is essentially used as an additional precaution, but not for the primary medical purpose.

We note, however, that the policy article involved in this case was not the only notice of CMS's application of the DME definition to CGM systems. On August 13, 2014, before the dates of service at issue, the two contractors responsible for DME claims posted a joint publication further elucidating the reasoning behind CMS's view that the then-available CGM devices failed to meet the statutory and regulatory definition of Medicare DME. In pertinent part, that document explains:

Current CGM systems are FDA-approved only as a secondary source for glucose monitoring. According to the FDA labeled indications, all CGM device readings must be confirmed with a capillary blood glucose monitor and users are cautioned against making insulin dosage changes based solely on CGM system determinations. Consequently, CGM devices are considered precautionary equipment. The Medicare Durable Medical Equipment Benefit excludes precautionary items from coverage; therefore, claims for CGM systems are denied as statutorily non-covered, no benefit.

Medicare covers necessary supplies used with covered items. When the base item is non-covered, the related supplies are also not covered. Claims for supplies used with CGM systems are denied as statutorily non-covered, no benefit.

Coverage and Correct Coding of Continuous Glucose Monitoring Devices: Joint DME MAC Publication, available at <a href="https://www.dmepdac.com/resources/articles/2014/08\_13\_14.html">https://www.dmepdac.com/resources/articles/2014/08\_13\_14.html</a> (last accessed May 7, 2018).

We recognize that a District Court decision (from another jurisdiction) remanded to the Council a case also involving the question of whether a CGM system was DME. Finigan v. Burwell, 189 F.Supp.3d 201 (D. Mass. 2016). That court rejected the conclusion that the ALJ was required to give "substantial deference" to a policy article analogous to the one involved here stating that a CGM is "precautionary." Finigan, 189 F.Supp.3d at 207-208. The court pointed out that a policy article addressing a benefit category is not the same as an LCD addressing medical necessity circumstances. Id. This distinction is correct, as we have explained earlier, and is critical to our analysis in that the definition of DME generally, not the individual use of a device, is key unlike LCD provisions.

However, the court then opined that 42 C.F.R. § 405.1062(a) does not require the ALJ to give substantial deference to the policy article (absent an explanation for deviating) because the regulation specifically applies to LCDs. Id. In fact, the regulation is broader than merely LCDs, stating that neither ALJs nor the Council are "bound by LCDs . . . or CMS program guidance, such as program memoranda and manual instructions, but will give substantial deference to these policies if they are applicable to a particular case." (Emphasis added). 405.1062 does not define the entire scope of appropriate deference to CMS interpretations of its statute and regulations. The purpose of section 405.1062 is to permit ALJs and the Council to decline to follow otherwise applicable policies where a "particular case" is found to present a good reason to disregard the general policy. 42 C.F.R. § 405.1062(b). A decision not to apply a policy in a particular beneficiary's situation does not have any effect on the validity of the policy and is based on individualized facts. Medicare Program: Changes to the Medicare Claims Appeal Procedures, 70 Fed. Reg. 11,420, at 11,457-58. This flexibility makes sense in dealing with questions of individual medical necessity which may arise in nearly infinite variety for which preset policies may not be able to fully take account.

The meaning of DME in the Act, as defined by regulation, is not a matter of applying policies to individual medical needs but of interpreting overarching benefit classifications. Substantial deference is due to a policy article which interprets whether an item falls within the definition of DME. 42 C.F.R § 405.1062. We conclude that CMS reasonably interpreted the regulatory definition of the scope of the DME benefits as excluding CGM devices which the FDA had not approved as sufficiently reliable to use as the basis of treatment decisions.

3. The CMS Ruling does not support coverage but rather bolsters the Council's conclusions here.

The 2017 Ruling expressly continues to recognize that "Medicare does not cover CGMs approved by the FDA for use as adjunctive devices to complement, not replace, information obtained from blood glucose monitors." CMS Ruling 1682-R at 6-7. CMS again explained that, in its view, "such devices are not used for making diabetic treatment decisions, such as changing one's diet or insulin dosage based solely on the readings of the CGM, and therefore, have not been covered under Medicare because they are not considered to serve the medical purpose of making diabetic treatment decisions." Id. at 7 (CGM devices of this type are referred to as "non-therapeutic).

The change which CMS Ruling 1682-R reflects is that the FDA newly approved a subset of CGM devices as capable of being used to determine treatment without blood testing for a glucose reading, in other words for "replacement of blood glucose monitors for diabetic treatment decisions." Id. at 8 (CGM monitors of this type are referred to as "therapeutic."). We conclude that, far from creating some basis for treating the appellant's non-therapeutic CGM system and supplies as DME, CMS Ruling 1682-R reinforces CMS's consistent interpretation of the definition of DME to mean that only CGM devices serving to provide or guide therapy directly are understood to be primarily and customarily used to serve a medical purpose under Medicare.

In sum, as set forth above, we agree with the ALJ that the CGM system the appellant used on the dates of service did not meet

<sup>&</sup>lt;sup>5</sup> Therapeutic CGM systems still require twice daily calibration so they do not eliminate the need for blood glucose monitoring entirely but the readings from a calibrated therapeutic CGM system may be relied upon for treatment purposes without seeking another blood glucose reading. *Id*.

the regulatory definition of DME and that the sensors and transmitter at issue are not covered by Medicare.

Liability

We note that section 1879 of the Act limits the liability of a beneficiary in certain cases where coverage for an item or service is denied under section 1862(a)(1)(A) of the Act. However, in this case, coverage is denied because the items at issue do not meet the definition of DME set forth in section 1861(n) of the Act. Therefore, section 1879's limitation on liability provisions do not apply in this case. See Medicare Claims Processing Manual, CMS Pub. 100-04, Ch. 30, § 20.2.2 (Section 1879 does not apply to "technical denials," such as cases where an item does not meet the definition of DME.). Accordingly, nothing in section 1879 of the Act precludes the supplier from billing the appellant for the non-covered items in this case.

### DECISION

For the above reasons, the Council concludes that Medicare will not cover the CGM sensors and transmitter provided to the appellant on July 11, 2016, and November 10, 2016, for use with a Dexcom G4 CGM system. The ALJ's decision is modified in accordance with the above.

MEDICARE APPEALS COUNCIL

eborah S. Samenow

Administrative Appeals Judge

bebbie K. Nobleman

Administrative Appeals Judge

Date: MAY 7 7 2018